McKESSON
Empowering Healthcare

510(k) SUMMARY
McKesson Israel Ltd.'s McKesson Cardiology™ Hemo

McKesson Israel Ltd.
4 HaNechoshet Street
Tel Aviv
Israel
69710

Contact Person: Tomer Levy, VP Engineering
Phone: +972 (0)3 7698000
Facsimile: +972 (0)3 6478593

DEC 05 2013

Date Prepared:	April 28, 2013
Name of the device	McKesson Cardiology™ Hemo
Common Name:	Cardiac monitor
Classification Name:	Monitor, Physiological, Patient, Without Arrhythmia Detection or Alarms
Classification Regulation	21 CFR § 870.2300
Classification Product code:	MWI
Subsequent Product code:	DQK
Device Class:	Class II
Predicate Device:	Medcon Ltd., Windsurfer (K050561), WITT BIOMEDICAL CORP Philips Xper Flex Cardio Physiomonitoring System/ Xper Information Management System (K101571)

Intended Use / Indications for Use

McKesson Cardiology™ Hemo is intended for complete physiological/hemodynamic monitoring, clinical data acquisition, medical image and data processing, and analytical assessment.

McKesson Cardiology™ Hemo is also intended for patient/procedural data management, such as documentation, logging, reporting, trending, storing, reviewing, carrying out clinical calculations and exporting various representations of the acquired data. Data may also be acquired from and/or sent to other devices, such as physiological monitoring systems, information management systems, image acquisition/storage devices, and other medical devices.

McKesson Cardiology™ Hemo is intended for use in the areas of: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology, and other areas where patient/procedural data management is needed.

User-adjustable alarms (both visual and audible) available in the system alert the operator to anomalous occurrences and facilitate timely responses.

Use of the system is not intended for unattended patient monitoring or in situations where arrhythmia detection is required.

Technological Characteristics

The McKesson Cardiology™ Hemo device is a hemodynamic monitoring system for monitoring vital signs, performing measurements and calculations, documenting procedure and patient data and interfacing to other systems and devices during and after procedures in the area of in the areas of: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology, and other areas where patient/procedural data management is needed.

McKesson Cardiology™ Hemo also acquires patient information from other hospital information systems and makes hemodynamic information available to them. It facilitates seamless interfacing with hospital information systems and cardiac image management, archiving and reporting systems.

McKesson Cardiology™ Hemo incorporates the FDA cleared the ARGUS PB vital signs monitoring device (K012226), manufactured by Schiller AG, which provides patient monitoring via:

- ECG leads
- Invasive Blood Pressure (non-McKesson transducers)
- SpO2 sensor
- Non-invasive blood pressure (NIBP) cuff
- Temperature probe
- Thermal Dilution Cardiac output temperature probe (connected to a non-McKesson Cardiac Output catheter)
- CO2 (connected to non-McKesson cannulas or intubation tubes)

Disposables and accessories (transducers, cannulas and intubation devices) are not part of the McKesson Cardiology™ Hemo system, but are supplied by the end user facility as required.

McKesson Cardiology™ Hemo is composed of:

- A control and documentation unit (Information System) that is used for administration, performing measurements, recording full disclosure, taking samples and entering procedure notes and overall data input and management of the patient and procedure data.
- A Clinical Unit that incorporates the 'Clinical System' and the 'Front-End' unit (which incorporates the Schiller Argus PB device - K012226). The clinical unit is responsible for acquiring, analyzing and displaying patient vitals and other pertinent clinical data. The data is displayed on monitors.

McKesson Cardiology™ Hemo uses an intuitive interface that clearly displays patient data, procedure data, waveforms and numeric values. The performing physician views the monitor, and conveys instructions and procedure notes to the technician, who operates the application using a touch screen, keyboard and mouse.

Performance Data

Verification and validation testing was performed on McKesson Cardiology™ Hemo to ensure it met all specifications. The device was further validated to ensure that it performs as intended. Performance testing was conducted to verify compliance with specified design requirements and relevant safety standards such as: IEC 60601-1, IEC 60601-1-2, IEC 60601-2-49 and IEC 60601-1-8. In all instances, McKesson Cardiology™ Hemo functioned as intended and the observed results demonstrate substantial equivalence with the predicate devices.

Substantial Equivalence

McKesson Cardiology™ Hemo is substantially equivalent to Medcon Ltd.'s Windsurfer (K050561), as well as Witt Biomedical Corp Philips Xper Flex Cardio Physiomonitoring System/ Xper Information Management System (K101571). McKesson Cardiology™ Hemo has the same intended use and similar indications, technological characteristics and principles of operation as the predicate devices.

The minor technological differences between McKesson Cardiology™ Hemo and its predicate devices raise no new issues of safety or effectiveness. Thus, McKesson Cardiology™ Hemo is substantially equivalent to previously- cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

December 5, 2013

Mckesson Israel Ltd.
Mr. Paul Sumner
Director, Regulatory Affairs
5995 Windward Parkway
Alpharetta, GA 30005 US

Re: K131497
Trade/Device Name: Mckesson Cardiology Hemo
Regulation Number: 21 CFR 870.1025
Regulation Name: Monitoring, Physiological, Patient (Without Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: MWI, DQK
Dated: October 22, 2013
Received: October 25, 2013

Dear Paul Sumner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

McKESSON
Empowering Healthcare

Indication for Use Statement

K131497

510(k) Number (if known):_____

Device Name: McKesson Cardiology™ Hemo

Indications for Use:

McKesson Cardiology™ Hemo is intended for complete physiological/hemodynamic monitoring, clinical data acquisition, medical image and data processing, and analytical assessment.

McKesson Cardiology™ Hemo is also intended for patient/procedural data management, such as documentation, logging, reporting, trending, storing, reviewing, carrying out clinical calculations and exporting various representations of the acquired data. Data may also be acquired from and/or sent to other devices, such as physiological monitoring systems, information management systems, image acquisition/storage devices, and other medical devices.

McKesson Cardiology™ Hemo is intended for use in the areas of: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology, and other areas where patient/procedural data management is needed.

User-adjustable alarms (both visual and audible) available in the system alert the operator to anomalous occurrences and facilitate timely responses.

Use of the system is not intended for unattended patient monitoring or in situations where arrhythmia detection is required.

Prescription Use (Part 21 CFR 801 Subpart D) ___X___ AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.12.05 16:23:18 -05'00'